

Exhibit 2

PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 20-1411

ANDREA SARDIS, As Administrator of the Estate of Evangelos Sardis, Deceased,

Plaintiff – Appellee,

v.

OVERHEAD DOOR CORPORATION,

Defendant – Appellant.

PRODUCT LIABILITY ADVISORY COUNCIL, INC.,

Amicus Supporting Appellant.

Appeal from the United States District Court for the Eastern District of Virginia, at
Richmond. John A. Gibney, Jr., District Judge. (3:17-cv-00818-JAG)

Argued: March 11, 2021

Decided: August 20, 2021

Before GREGORY, Chief Judge, AGEE, and DIAZ, Circuit Judges.

Reversed and remanded with instructions by published opinion. Judge Agee wrote the
opinion, in which Chief Judge Gregory and Judge Diaz joined.

ARGUED: Sarah Virginia Bondurant Price, MCGUIREWOODS LLP, Richmond, Virginia, for Appellant. L. Steven Emmert, SYKES, BOURDON, AHERN & LEVY, PC, Virginia Beach, Virginia, for Appellee. **ON BRIEF:** Michael W. Stark, MCGUIREWOODS LLP, Richmond, Virginia; Martin A. Conn, Matthew J. Hundley, Lisa M. McMurdo, MORAN REEVES & CONN PC, Richmond, Virginia, for Appellant. Peter C. Grenier, GRENIER LAW GROUP PLLC, Washington, D.C.; Andrew G. Slutkin, Ethan Nochumowitz, SILVERMAN THOMPSON SLUTKIN & WHITE, Baltimore, Maryland, for Appellee. Robert L. Wise, Jason R. Hodge, Richmond, Virginia, Susan E. Burnett, BOWMAN AND BROOKE LLP, Austin, Texas, for Amicus Curiae.

AGEE, Circuit Judge:

Federal Rule of Evidence 702 appoints trial judges as “gatekeepers of expert testimony” to protect the judicial process from “the potential pitfalls of junk science.” *United States v. Bonner*, 648 F.3d 209, 215 (4th Cir. 2011). If a trial court abdicates that duty by opening the gate indiscriminately to *any* proffered expert witness—particularly one with whom it recognizes “legitimate concerns,” J.A. 287—it risks exposing jurors to “dubious scientific testimony” that can ultimately “sway[]” their verdict, *Nease v. Ford Motor Co.*, 848 F.3d 219, 231 (4th Cir. 2017) (quoting *In re Zurn Pex Plumbing Prods. Liab. Litig.*, 644 F.3d 604, 613 (8th Cir. 2011)). That risk is notably amplified in products liability cases, for “expert witnesses necessarily may play a significant part” in establishing or refuting liability. *Chase v. Gen. Motors Corp.*, 856 F.2d 17, 20 (4th Cir. 1988).

Appellee Andrea Sardis, in her capacity as the Administrator of the Estate of her late husband, Evangelos Sardis (“the Estate”), asserted various products liability claims against Appellant Overhead Door Corporation (“ODC”) relating to Mr. Sardis’ tragic death in a work-related accident in June 2016. But the only probative evidence supporting the Estate’s claims came from two expert witnesses, neither of whom offered relevant or reliable opinions. Nonetheless, the district court permitted the jurors to hear their testimony, finding that cross-examination was the proper, and only, tool to vet any relevance or reliability factors. On the basis of that testimony, the jury awarded the Estate a multi-million-dollar verdict.

That verdict is the result of the district court’s abuse of discretion in admitting the Estate’s expert testimony. Without it, the Estate offered insufficient admissible evidence

as a matter of law to prevail on any of the four claims submitted to the jury. We therefore reverse the judgment in this case, and remand with instructions that judgment be entered in favor of ODC as to each of the Estate’s claims.

I.

A.

ODC designs and manufactures garage doors and the metal hoods those doors are installed in, and then sells these products through a network of independent distributors. ODC also designs and manufactures the packaging used for shipping these products. The packaging—not the garage doors or hoods—is the focus of this case.

For thirty years, until 2014, ODC shipped its garage door hoods in rectangular prism-shaped containers. The entire container was made of a double-wall corrugated material, and the two “ends” of the container (the two square ends to which all four of the rectangular “sides” connected) contained handhold “punchouts” in the material. ODC intended for workers to use, and workers in fact used, these handholds to push and pull the containers as necessary for storage and transit. ODC never received a report of a worker ripping a handhold, but it did receive complaints that the corrugated material would collapse during transit, damaging the hoods inside.

In response to these complaints, ODC redesigned its garage door hood containers in December 2014. It kept the same rectangular prism shape, but made two important modifications. First, it replaced the double-wall corrugated material on the sides with triple-wall corrugated material. Second, it replaced the double-wall corrugated material on

the ends with wood slats. Staples connected each of the four triple-wall corrugated sides to two vertical pieces of wood on either “end.” The square “ends” were comprised of several horizontal pieces of wood that were nailed into the two vertical wood slats. ODC incorporated the “handhold” design from its old container design by omitting one horizontal wood piece on each end. A photograph of an exemplar container, J.A. 1243, is reproduced below.



Prior to using this new container design for shipping its goods, ODC performed some field testing. According to Bradley Knable, ODC’s corporate designee, the testing included workers pushing and pulling the containers using those handholds, although there was no specific test of the maximum strength of the new handholds. The new design overall performed to ODC’s satisfaction. ODC then shipped garage door hoods in these new containers to select customers. ODC asked for feedback on the containers, and received no complaints about the new container or its handholds.

B.

Mr. Sardis began working for Washington Overhead Door, Inc. (“WOD”), an ODC distributor, in June 2016. On June 6, 2016, he and his training supervisor, Keith Lawrence, were asked to transport an ODC garage door hood to a work site. The hood was shipped in a post-2014 ODC container (hereinafter “the Container”), which was loaded onto a ladder rack in the bed of a WOD service truck that Lawrence operated. At the work site, Lawrence tried to remove the Container from the truck with a forklift, but the Container became unbalanced on the forklift’s tines, making it unsafe to unload. Mr. Sardis then climbed onto the ladder rack and tried to adjust the Container on the forklift tines by pulling on one of its handholds. Lawrence recalled seeing Mr. Sardis standing in a “C position,” in which his hands were directly over his feet, and his body was curved in a “C”-shape. J.A. 665–66. When Mr. Sardis pulled, the wood slat constituting the handhold broke off, causing him to fall off the ladder rack and hit his head on the pavement nine feet below. He succumbed to his injuries two weeks later. The Container was photographed immediately after the accident, but it was not preserved, to the fault of neither party. Thus, neither party could test or otherwise examine the Container involved in Mr. Sardis’ accident.¹

¹ During discovery, the Estate requested that ODC produce at least three containers identical to the one involved in Mr. Sardis’ accident. ODC responded that it did not have any such container in its possession because it only manufactures them on-demand, but offered to construct three replicas of the Container. The Estate rejected this offer, claiming it “would have no way of knowing whether ODC made subtle changes to its design intended to strengthen the crates and/or the handholds, rendering any such testing wholly unreliable.” Pl.’s Opp. to Def.’s Mot. to Exclude Dr. Singh at 24, *Sardis v. Overhead Door Corp.*, No. 3:17-cv-00818-JAG (E.D. Va. filed Nov. 15, 2018), ECF No. 75.

C.

After Mr. Sardis' death, the Estate sued ODC in federal court, invoking the district court's diversity jurisdiction.² The Estate asserted four causes of action under Virginia products liability law: (1) a general negligence claim; (2) a design defect claim; (3) a breach of implied warranty claim; and (4) a failure to warn claim.³ Essentially, the Estate alleged that ODC was negligent in designing the Container's handholds, and that this defective design caused Mr. Sardis' injuries. Alternatively, the Estate alleged that ODC had a duty to warn foreseeable users of the Container to not rely on the handholds for pulling it, and that had Mr. Sardis been warned, he would not have been injured. The Estate offered Sher Paul Singh, Ph.D., as its sole expert for the design defect claim; and Michael S. Wogalter, Ph.D., as the sole expert for the failure to warn claim.

Dr. Singh, a packaging design engineer, opined that the Container should have been designed according to what he claimed was the relevant industry standard, American Society of Testing and Materials Standard #D6039 ("ASTM D6039"). He opined that the Container failed to satisfy this standard in two ways: (1) the handholds should not have been included in the design; and (2) the Container should have been designed with end "cleats," or pieces of lumber or plywood vertically nailed onto the wood end pieces on the

² The district court properly had diversity jurisdiction over this case. Mr. Sardis was domiciled in Virginia, and so is his Estate; ODC maintains its principal place of business in Texas; and the Estate's Complaint sought damages well in excess of \$75,000. *See* 28 U.S.C. § 1332(a)(1).

³ The Estate's Complaint asserted a fifth cause of action based on an alleged manufacturing defect, but it abandoned this claim before trial.

outside of the Container. Dr. Singh also testified that ODC breached industry standards by failing to test the Container prior to placing it in the stream of commerce. Finally, without performing any testing or citing to any published literature, he opined that these failures proximately caused Mr. Sardis' death.

The Estate also offered the expert testimony of Dr. Wogalter for its failure to warn claim. Dr. Wogalter described himself as an expert on "human factors," which he said was "a discipline of study that deals with the design of products and systems based on people's abilities and limitations to promote productivity, satisfaction, and safety." J.A. 96, 555. He offered three opinions: (1) ODC should have done a "hazard analysis" (which entails, *inter alia*, field and laboratory testing and soliciting feedback from consumers) to ascertain if its new handheld design created new dangers that would require warnings; (2) the lack of warnings about the hazards of pulling on the wooden handholds made it unreasonably dangerous; and (3) ODC's failure to perform a hazard analysis and to warn consumers not to pull on the Container's handholds proximately caused Mr. Sardis' death.

Before trial, ODC filed a motion in limine to exclude both experts' testimony as irrelevant and unreliable. *See Daubert v. Merrell Dow Pharms.*, 509 U.S. 579 (1993). The district court denied the motion as to both experts in a cursory fashion. Making no relevancy determinations, it held only that ODC's reliability concerns lacked merit because "[a] lack of testing . . . affects the weight of the evidence,' not its admissibility." *E.g.*, J.A. 289 (citation omitted). Instead, the district court opined that ODC could address its concerns through "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof." *Id.* (alteration in original) (citation omitted).

D.

After the jury rendered a \$4.84 million verdict in the Estate’s favor on all four claims for relief, ODC filed a renewed motion for judgment as a matter of law under Federal Rule of Civil Procedure 50(b). ODC reasserted that both Drs. Singh and Wogalter provided irrelevant and unreliable opinions, and that the district court should have stricken their testimony at trial. In ODC’s view, with or without their testimony, the Estate could not prevail on its claims as a matter of law.

Beginning with Dr. Singh and the Estate’s design defect claim, the district court rejected ODC’s renewed *Daubert* challenges to Dr. Singh’s testimony as only “‘affect[ing] the weight of the evidence,’ not its admissibility.” J.A. 1179 (citation omitted); J.A. 1182. On the merits of the design defect claim, the court concluded that Dr. Singh provided sufficient testimony to show that ASTM D6039 was the applicable industry standard for the Container’s design, and that “the [C]ontainer fell short of that standard’s specifications.” J.A. 1181. It further found that despite “some flaws” in Dr. Singh’s proximate causation opinion, his testimony “gave the jury sufficient evidence to conclude that the container’s defective design proximately caused [Mr.] Sardis’ death.” J.A. 1182.

ODC also argued that Dr. Wogalter’s testimony was inadmissible under *Daubert* because his opinions all relied on the irrelevant point that ODC should have known of the dangers that its handheld design posed. According to ODC, in order to prevail on a failure to warn claim, Virginia law required ODC to have *reason* to know of the dangers, but Dr. Wogalter provided no such testimony addressing that standard.

The district court made no explicit *Daubert* findings as to Dr. Wogalter, concluding only that there was sufficient evidence to support the jury's failure to warn verdict. Citing Mr. Knable's testimony that ODC did not "ever consider the potential dangers that its packaging or crates can pose to others," and Dr. Wogalter's testimony that ODC had to "solicit feedback" from users of the Container about the handhold's dangers, the court found that a reasonable jury could conclude that ODC "violated its 'general duty to make reasonable inferences from relevant and reasonably available facts.'" J.A. 1185 (citation omitted). This testimony, the court explained, sufficiently supported the finding that ODC "had a 'reason to know' of the [C]ontainer's dangers." J.A. 1185–86. The court did not, however, address the issue of proximate causation.

ODC lastly challenged the sufficiency of the evidence supporting the jury's verdicts on the other two claims for relief, the general negligence claim and the breach of the implied warranty of merchantability claim. The district court rejected both arguments, however, deeming the evidence sufficient to support both verdicts. ODC thereafter timely filed a notice of appeal, and we have jurisdiction pursuant to 28 U.S.C. § 1291.

II.

Rule 50(b) permits a party to bring a renewed motion for judgment as a matter of law after the jury has rendered its verdict. If that motion is denied, the moving party is entitled to assert those same arguments on appeal, Fed. R. Civ. P. 50(e), and our subsequent review is de novo, *Sloas v. CSX Transp., Inc.*, 616 F.3d 380, 392 (4th Cir. 2010). In our analysis, we must view the evidence in the light most favorable to the nonmoving party,

id., without weighing it or making any credibility determinations, *Chaudhry v. Gallerizzo*, 174 F.3d 394, 404–05 (4th Cir. 1999). Our task is to determine “whether there was a *legally sufficient evidentiary basis* for a reasonable jury” to render the verdict that it did. *ABT Bldg. Prods. Corp. v. Nat’l Union Fire Ins. Co. of Pittsburgh*, 472 F.3d 99, 113 (4th Cir. 2006) (emphasis added). This requires us to first excise any evidence that was erroneously admitted during trial, because “[i]nadmissible evidence contributes nothing to a ‘legally sufficient evidentiary basis.’” *Weisgram v. Marley Co.*, 528 U.S. 440, 453–56 (2000). If the district court erred in denying judgment as a matter of law, then we have the discretion to (1) “order a new trial,” (2) “direct the trial court to determine whether a new trial should be granted,” or (3) “direct the entry of judgment” in the moving party’s favor. Fed. R. Civ. P. 50(e).

III.

On appeal, ODC asserts that the district court reversibly erred in admitting the expert testimony of Drs. Singh and Wogalter under Federal Rule of Evidence 702. It argues that the district court first erred by delegating the determination of expert witness relevance and reliability to the jury without performing any *Daubert* analysis. On the merits, ODC contends that both experts’ opinions were irrelevant because Dr. Singh offered no relevant industry standard, and Dr. Wogalter’s testimony was incompatible with Virginia’s failure to warn jurisprudence. Further, ODC posits that both experts’ failure to test or otherwise authenticate their proximate causation opinions rendered them unreliable. Since the

experts' testimony was inadmissible, according to ODC, the Estate cannot establish any design defect or reason for ODC to have known of the Container's alleged dangers.

The Estate counters that the district court properly allowed the jury to consider ODC's challenges to Drs. Singh's and Wogalter's testimony. And even if those experts' testimony was inadmissible, the Estate maintains that the other admissible evidence at trial sufficiently supported the jury's verdict on each claim for relief.

We agree with ODC. The district court erred at the motion in limine stage when it improperly abdicated its critical gatekeeping role to the jury and admitted Drs. Singh's and Wogalter's expert testimony without engaging in the required Rule 702 analysis. That error was harmful. Had the district court faithfully executed its *Daubert* responsibilities before or after the jury's verdict, our precedent would have compelled it to exclude both experts' testimony. And without that expert testimony, the Estate failed to meet its evidentiary burden on each cause of action submitted to the jury.

A.

Before addressing the merits of the arguments on appeal, it is helpful to provide an overview of Virginia products liability law.

"Virginia has not adopted a strict liability regime for products liability." *Evans v. Nacco Materials Handling Grp., Inc.*, 810 S.E.2d 462, 469 (Va. 2018). Instead, plaintiffs may pursue a products liability remedy "under a theory of implied warranty of merchantability or under a theory of negligence." *Id.* To prevail on either theory, a plaintiff must prove "(1) that the goods were unreasonably dangerous either for the use to which they would ordinarily be put or for some other reasonably foreseeable purpose, and (2) that

the unreasonably dangerous condition existed when the goods left the defendant's hands.”

Id. (quoting *Featherall v. Firestone Tire & Rubber Co.*, 252 S.E.2d 358, 367 (Va. 1979)).

A product is “unreasonably dangerous” if it is defectively manufactured, defectively designed, or “unaccompanied by adequate warnings concerning its hazardous properties.”

Id. (quoting *Morgen Indus., Inc. v. Vaughan*, 471 S.E.2d 489, 492 (Va. 1996)).

To prevail on a design defect claim, a plaintiff must show that the manufacturer “owes a legally recognized duty to design” a product in a certain way to ensure that the product “is reasonably safe for the purpose for which it is intended.” *Holiday Motor Corp. v. Walters*, 790 S.E.2d 447, 454–55 (Va. 2016). Whether such a duty exists is a question of law for the court, not the jury, *id.* at 454, and is informed by three kinds of evidence: (1) governmental safety standards; (2) industry practices; and (3) reasonable consumer expectations. *Evans*, 810 S.E.2d at 469–70.

If a plaintiff successfully establishes a duty to construct a product in a particular manner, the manufacturer breaches that duty if the product does not conform to that standard. *Holiday Motor*, 790 S.E.2d at 455 & n.14; *see also Evans*, 810 S.E.2d at 469–70. Whether the product failed to conform to the established standard is a fact question for the jury to resolve. *See Morgen Indus.*, 471 S.E.2d at 492.

Distinctly, failure to warn claims recognize that “[a] product may . . . suffer from no design defect, but nevertheless require a warning to consumers about a hidden danger.” *Evans*, 810 S.E.2d at 472. To prevail on such a claim, a plaintiff must prove that the manufacturer:

- (a) knows or has reason to know that the [product] is or is likely to be dangerous for the use for which it is supplied, and
- (b) has no reason to believe that those for whose use the [product] is supplied will realize its dangerous condition, and
- (c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

Funkhouser v. Ford Motor Co., 736 S.E.2d 309, 313 (Va. 2013) (quoting *Featherall*, 252 S.E.2d at 366).

B.

We begin with ODC's argument that the district court abused its discretion in admitting Drs. Singh's and Wogalter's expert testimony. We review a district court's decision to admit expert testimony for an abuse of discretion. *McKiver v. Murphy-Brown, LLC*, 980 F.3d 937, 958 (4th Cir. 2020). And in conducting our Rule 50(b) analysis, we "must first excise inadmissible evidence," as "such evidence 'contributes nothing to a legally sufficient evidentiary basis.'" *Hodges v. Mack Trucks Inc.*, 474 F.3d 188, 193 (5th Cir. 2006) (quoting *Weisgram*, 528 U.S. at 454).

Rule 702 permits expert testimony if that testimony is (1) helpful to the jury in understanding the evidence or determining a fact at issue, (2) "based on sufficient facts or data," (3) "the product of reliable principles and methods," and (4) the product of a "reliabl[e] appli[cation] of th[ose] principles and methods to the facts of the case." Rule 702 thus "imposes a special gatekeeping obligation on the trial judge" to "ensur[e] that an expert's testimony both rests on a *reliable* foundation and is *relevant* to the task at hand." *Nease*, 848 F.3d at 229–30 (quoting *Daubert*, 509 U.S. at 597).

An expert's opinion is relevant if it has "a valid scientific connection to the pertinent inquiry." *Belville v. Ford Motor Co.*, 919 F.3d 224, 232 (4th Cir. 2019) (quoting *Daubert*, 509 U.S. at 592). This ensures that the expert "helps 'the trier of fact to understand the evidence or to determine a fact in issue.'" *Nease*, 848 F.3d at 229 (citation omitted). Simply put, if an opinion is not relevant to a fact at issue, *Daubert* requires that it be excluded.

But even if relevant, an opinion must also be sufficiently reliable. Reliability is a "flexible" inquiry that focuses on "the principles and methodology" employed by the expert. *Daubert*, 509 U.S. at 594–95. Specifically, district courts must ensure that an expert's opinion is "based on scientific, technical, or other specialized *knowledge* and not on belief or speculation." *Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 250 (4th Cir. 1999). And to the extent an expert makes inferences based on the facts presented to him, the court must ensure that those inferences were "derived using scientific or other valid methods." *Id.*

Daubert provides four, non-exhaustive "guideposts" to aid in the required reliability analysis: (1) whether the expert's theory or technique "can be (and has been) tested"; (2) "whether the theory or technique has been subjected to peer review and publication"; (3) "the known or potential rate of error" inherent in the expert's theory or technique; and (4) whether the expert's methodology is generally accepted in his field of expertise. *Nease*, 848 F.3d at 229 (quoting *Daubert*, 509 U.S. at 593–94). But this list "neither necessarily nor exclusively applies to all experts or in every case," as the relevance of some factors can "depend[] on the nature of the issue, the expert's particular expertise, and the subject of his testimony." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141, 150 (1999) (citation

omitted). Accordingly, trial courts are typically given “broad latitude” to determine which of these factors (or some other unspecified factors) are “reasonable measures of reliability in a particular case.” *Nease*, 848 F.3d at 229 (quoting *Kumho Tire*, 526 U.S. at 153). But that broad discretion does not allow a district court to delegate the issue to the jury.

As we explain below, the district court abused its discretion initially when it failed to perform any *Daubert* analysis and ruled that the issues of relevance and reliability impacted only the weight of the experts’ testimony, not their admissibility. That error was harmful for two independent reasons. First, without Drs. Singh’s and Wogalter’s testimony, the Estate could not have prevailed on any of its claims as a matter of law. And second, assuming that the court had considered the merits of ODC’s *Daubert* challenges in ruling on ODC’s post-trial Rule 50(b) motion, it abused its discretion in refusing to strike Drs. Singh’s and Wogalter’s testimony for both offered irrelevant and unreliable opinions.

1.

a.

We begin with ODC’s argument that the district court failed to perform its gatekeeping function as to both experts.

After the Supreme Court’s seminal decisions in *Daubert* and *Kumho Tire*, Rule 702 was amended specifically to “affirm[] the trial court’s role as gatekeeper.” Fed. R. Evid. 702 advisory committee’s note to 2000 amendments. So when a party challenges an opposing expert’s testimony as irrelevant, the court must satisfy itself that the proffered testimony is relevant to the issue at hand, for that is “a *precondition* to admissibility.” *Daubert*, 509 U.S. at 592 (emphasis added). And if that expert’s proffered evidence is

further alleged to be unreliable, then “the trial judge must determine whether the testimony has ‘a reliable basis in the knowledge and experience of the relevant discipline.’” *Kumho Tire*, 526 U.S. at 149 (alteration omitted) (quoting *Daubert*, 509 U.S. at 592). While district courts have “broad discretion” in analyzing reliability, “such discretion does not include the decision ‘to abandon the gatekeeping function.’” *Nease*, 848 F.3d at 230 (quoting *Kumho Tire*, 526 U.S. at 158–59 (Scalia, J., concurring)). “Rather, it is discretion to choose among *reasonable* means of excluding expertise that is *fausse* and science that is junky.” *Kumho Tire*, 526 U.S. at 159 (Scalia, J., concurring). Thus, a district court abuses its discretion if it fails to ensure that a proffered expert opinion is “sufficiently relevant and reliable *when it is submitted to the jury*.” *Nease*, 848 F.3d at 231.

The district court’s ruling on ODC’s motion in limine cursorily dismissed each of ODC’s reliability and relevance arguments as only going to weight, not admissibility. Although the court recognized “*legitimate concerns*” with Dr. Wogalter’s proffered testimony, it nonetheless deemed those concerns solely a subject for cross-examination. J.A. 287–88 (emphasis added). Despite ODC’s request, the district court failed to undertake any *Daubert* analysis. Just as in *Nease*, “[t]he court did not use *Daubert*’s guideposts or any other factors to assess the reliability of [Drs. Singh’s and Wogalter’s] testimony, and the court did not make any reliability findings.” 848 F.3d at 230. Instead, it reflexively “[found] that [ODC]’s arguments go to the weight the jury should afford [Dr. Singh’s] testimony, not its admissibility.” *Id.* at 230–31 (first alteration in original). By doing so, the court “abandoned its gatekeeping function,” thereby abusing its discretion. *Id.* at 230.

The court similarly erred in ruling on ODC's post-trial Rule 50(b) motion. As to Dr. Singh, the district court doubled down, again finding that ODC's challenges went to the weight of the testimony, not admissibility. It pointed out that ODC "vigorously cross-examined Dr. Singh" on his failure to test his theories, but "the jury apparently found Dr. Singh's opinions credible." J.A. 1180, 1182. But credibility is entirely distinct from reliability and relevancy, which are *preconditions* to the admissibility of expert testimony. *Nease*, 848 F.3d at 229. While cross-examination may be a proper tool to determine which of two competing experts' theories more credibly explains an event, even a "'thorough and extensive examination' does not ensure the reliability" or relevance "of [an] expert's testimony." *Id.* at 231 (citation omitted). And while the court's opinion on the failure to warn claim considered Dr. Wogalter's testimony as part of the evidentiary basis supporting the jury's verdict, it never addressed ODC's challenges to Dr. Wogalter's proximate causation opinions, and never made any direct relevance or reliability rulings. Thus, as to both experts, the district court improperly "delegate[d] [its] gatekeeping responsibility to the jury," and thereby abused its discretion. *Id.*

At oral argument, the Estate posited that to the extent the district court did not make explicit its relevance and reliability findings, those were implicit in the ultimate ruling that both experts could testify. That is plainly insufficient. Where the admissibility of expert testimony is specifically questioned, Rule 702 and *Daubert* require that the district court make explicit findings, whether by written opinion or orally on the record, as to the challenged preconditions to admissibility. *United States v. Ruvalcaba-Garcia*, 923 F.3d 1183, 1190 (9th Cir. 2019) ("[T]he district court's ruling at most suggests an implicit

finding of reliability, which is not sufficient. To satisfy its gatekeeping duty under *Daubert*, the court must make an explicit reliability finding.” (citations and internal quotation marks omitted)); *Carlson v. Bioremedi Therapeutic Sys., Inc.*, 822 F.3d 194, 201 (5th Cir. 2016) (“At a minimum, a district court must create a record of its *Daubert* inquiry and articulate its basis for admitting expert testimony.” (alterations, citation, and internal quotation marks omitted)); *Gayton v. McCoy*, 593 F.3d 610, 616 (7th Cir. 2010) (“[T]he court must provide more than just conclusory statements of admissibility or inadmissibility to show that it adequately performed its gatekeeping function.”).

The district court did none of this, despite voicing its concerns with both experts during trial. *See, e.g.*, J.A. 501, 504 (pointing out that Dr. Singh’s reliance on ASTM D6039 might be “comparing apples and oranges,” but nonetheless deciding to “leave [the parties] to fight that out” in front of the jury); J.A. 573–74 (demanding that Dr. Wogalter provide “more detail” into the hazard analysis process “so that we can figure out whether there is a likelihood of good results,” but then discovering that there is no “existing literature” on the subject, and no analogous example of a hazard analysis performed on a similar container). Without the explicit findings required under *Daubert*, “it is impossible on appeal to determine whether the district court carefully and meticulously reviewed the proffered evidence or simply made an off-the-cuff decision to admit the expert testimony.” *Smith v. Jenkins*, 732 F.3d 51, 64 (1st Cir. 2013) (alteration and citation omitted). Accordingly, we hold that the district court failed to satisfy Rule 702’s gatekeeping requirement and that failure was an abuse of discretion.

We conclude with one final observation. Our insistence on district courts' compliance with Rule 702's plain gatekeeping requirement stems not from an arbitrary adherence to a procedural formality. Rather, because Rule 702 grants experts "wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation," "[e]xpert evidence can be both powerful and quite misleading." *Daubert*, 509 U.S. at 592, 595 (citations and internal quotation marks omitted). As such, "the importance of [the] gatekeeping function cannot be overstated." *United States v. Barton*, 909 F.3d 1323, 1331 (11th Cir. 2018) (citation and internal quotation marks omitted).

That much is confirmed by the Advisory Committee on Evidence Rules' current proposal to amend Rule 702. On April 30, 2021, the Committee unanimously approved a proposal to amend Rule 702, part of which is motivated by its observation that in "a number of federal cases . . . judges did not apply the preponderance standard of admissibility to [Rule 702's] requirements of sufficiency of basis and reliable application of principles and methods, instead holding that such issues were ones of weight for the jury." Advisory Comm. on Evidence Rules, *Agenda for Committee Meeting* 17 (Apr. 30, 2021) [saved as ECF opinion attachment]. In order to address this "pervasive problem," *id.* at 18, both of the current draft amendments to Rule 702 would contain the following language in the advisory committee's notes:

[U]nfortunately many courts have held that the critical questions of the sufficiency of an expert's basis [for his testimony], and the application of the expert's methodology, are generally questions of weight and not admissibility. These rulings are an incorrect application of Rules 702 and 104(a) and are rejected by this amendment.

Id. at 105, 107. That clearly echoes the existing law on the issue. *See, e.g., Daubert*, 509 U.S. at 589 (“[U]nder the Rules the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.”); *Kumho Tire*, 526 U.S. at 147 (extending *Daubert* to “all expert testimony”); Fed. R. Evid. 702 advisory committee’s note to 2000 amendments (“The trial court’s gatekeeping function applies to testimony by any expert.”). Consistent with that existing law—and in accordance with the Committee’s pending rule—we confirm once again the indispensable nature of district courts’ Rule 702 gatekeeping function in all cases in which expert testimony is challenged on relevance and/or reliability grounds.

b.

As with any evidentiary error, we review a district court’s abdication of its gatekeeping role for harmless error and require a new trial “only when the admission of evidence affected the substantial rights of a party.” *Wickersham v. Ford Motor Co.*, 997 F.3d 526, 531 (4th Cir. 2021). That is, if we can say “with fair assurance, after pondering all that happened without stripping the erroneous action from the whole, that the judgment was not substantially swayed by the error,” then we must affirm. *Taylor v. Va. Union Univ.*, 193 F.3d 219, 235 (4th Cir. 1999) (en banc) (alteration omitted) (quoting *United States v. Heater*, 63 F.3d 311, 325 (4th Cir. 1995)), *abrogated on other grounds by Desert Palace, Inc. v. Costa*, 539 U.S. 90 (2003). On the record before us, we cannot say that the district court’s abdication of its gatekeeping role was harmless.

In the ordinary run of cases, we deem the erroneous admission of expert testimony harmless if after excising the erroneously admitted expert testimony there remains

sufficient admissible evidence to uphold the jury's verdict. *See Wickersham*, 997 F.3d at 531–32 (deeming the admission of expert testimony harmless error because of the admission of similar testimony from other expert and non-expert witnesses). But that is not the case here. As we explain in greater detail in Part IV, *infra*, Drs. Singh and Wogalter were the only experts to offer the evidence necessary to establish the Estate's causes of action. We therefore cannot say that the district court's error here was harmless in this regard.

We had no cause to address in *Nease* the precise parameters of how a district court's abdication of its gatekeeping function becomes harmful error. We do so now and look to our sister circuits for guidance. That review uncovers two different approaches to the harmless error inquiry. We need not decide which is the "proper" one to follow (assuming there is one), because the district court's error here is harmful under either path.

First, some courts focus solely on whether the erroneously admitted expert testimony swayed the jury's verdict. *See, e.g., Carlson*, 822 F.3d at 202; *UGI Sunbury LLC v. A Permanent Easement for 1.7575 Acres*, 949 F.3d 825, 834–36 (3d Cir. 2020); *United States v. Valencia-Lopez*, 971 F.3d 891, 902 (9th Cir. 2020). The Fifth Circuit's decision in *Carlson* is the most instructive as that court similarly considered a district court's abdication of its *Daubert* gatekeeping function in a products liability case. 822 F.3d at 200–01. Specifically, "the district court disregarded its gatekeeping function to determine the admissibility of evidence outside of the presence of the jury" by conclusorily deeming the testimony of the defendant's expert witness, Dr. Durrett, admissible and instructing the

jury that “[w]hatever weight you give to this witness’s testimony, just like every witness, that’s strictly up to you.” *Id.* at 201.

Without considering the merits of the plaintiff’s underlying *Daubert* challenge, the Fifth Circuit held that the district court’s failure to fulfill its gatekeeping requirement was *not* harmless. *Id.* at 202. It pointed out that after the close of the plaintiff’s case-in-chief, the plaintiff defeated the defendant’s motion for judgment as a matter of law, meaning that there was “a legally sufficient evidentiary basis to find for” the plaintiff. *Id.* (citation omitted). But after the defendant called its only witness, the challenged expert witness, Dr. Durrett, the jury rendered a verdict for the defendant. *Id.* Because Dr. Durrett’s testimony was the *only* evidence that could have supported the jury’s verdict for the defendant, the court reasoned, “it is not credible to categorize the admission of Dr. Durrett’s testimony as harmless.” *Id.*; *see also UGI Sunbury LLC*, 949 F.3d at 834–36 (holding that the district court’s abdication of its gatekeeping role during a bench trial was harmful because the court ultimately relied on that expert testimony in awarding damages to the plaintiff); *Valencia-Lopez*, 971 F.3d at 902 (holding that the district court’s failure to subject the Government’s challenged expert witness to any *Daubert* scrutiny was harmful because that expert’s testimony “went ‘to the heart’ of the most important issue in the case,” the viability of the defendant’s duress defense, and it further undercut the credibility of both the defendant and his own retained expert).

Carlson is virtually indistinguishable from the case before us. Again, as we explain in Part IV, *infra*, all of the Estate’s claims fail as a matter of law without Drs. Singh’s and Wogalter’s testimony, so their testimony necessarily must have “substantially swayed” the

jury's verdict for the Estate. *See Taylor*, 193 F.3d at 235. In these circumstances, then, "it is not credible to categorize the admission of [their] testimony as harmless." *Carlson*, 822 F.3d at 202. Thus, under this approach, the district court's *Daubert* failure is harmful error and would, at minimum, require us to reverse its Rule 50(b) decision.

Other circuits allow for a more particular harmless review, permitting a reviewing court to make substantive findings of relevance and reliability if the record on appeal is sufficiently developed. *See Estate of Barabin v. AstenJohnson, Inc.*, 740 F.3d 457, 467 (9th Cir. 2014) (en banc), *overruled on other grounds by United States v. Bacon*, 979 F.3d 766, 770 (9th Cir. 2020) (en banc); *accord StorageCraft Tech. Corp. v. Kirby*, 744 F.3d 1183, 1190–91 (10th Cir. 2014). In an opinion authored by then-Judge Gorsuch, the Tenth Circuit endorsed this approach because if the expert's testimony turned out to be admissible on the merits, "it would be pointless to require a new trial at which the very same evidence can and will be presented again." *StorageCraft*, 744 F.3d at 1191. Alternatively, that inquiry may reveal that the challenged expert's testimony was *inadmissible*, and "if such a finding leaves insufficient evidence, the court 'may direct entry of judgment as a matter of law.'" *Bacon*, 979 F.3d at 769 (quoting *Barabin*, 740 F.3d at 467); *see* Fed. R. Civ. P. 50(e). If the record is insufficient for the reviewing court to make those findings, however, it is left to the panel's discretion to determine how to remedy the error. *Bacon*, 979 F.3d at 769–70.

Applying this approach and given the extensive examination undertaken of Drs. Singh and Wogalter during trial, we find that the record allows us to adequately review the merits of ODC's *Daubert* challenges. And as explained below, that review demonstrates

that the district court erred in failing to strike Drs. Singh's and Wogalter's testimony because both experts offered irrelevant and unreliable testimony.

Therefore, under either approach, the district court's *Daubert* gatekeeping error was not harmless.

2.

We now turn our attention to the merits of ODC's *Daubert* challenges beginning with Dr. Singh's expert testimony. Before addressing the application of the relevance and reliability requirements, we pause briefly to provide additional background on his substantive testimony.

a.

As noted, Dr. Singh offered several opinions during his testimony. He first testified that the Container was required to comply with the design standards set forth in ASTM D6039. The Container's design breached those standards, he opined, because it had handholds, and because there were no end cleats on the outside of the Container to reinforce the handholds. He further opined that ODC breached industry standards that required it to test the Container design prior to placing the Container in the stream of commerce. Finally, he stated that all of these shortcomings proximately caused Mr. Sardis' death.

As to the first opinion, regarding the governing standard, Dr. Singh explained that the ASTM promulgates a wide variety of design standards that govern both the domestic and international packaging industries. ASTM D6039 is entitled, "Standard Specification for Open and Covered Wood Crates." J.A. 154. It "covers five types and two styles of open and one type, and one style of covered wood crates designed for net loads not exceeding

4000 lb.” J.A. 154 (ASTM D6039 § 1.1). It defines a “crate” as “a container with structural framework fastened together to form a rigid structure enclosure, typically having an open construction concept with little or no panel support.” J.A. 155 (ASTM D6039 § 3.2.4).

Dr. Singh opined that ODC’s Container qualified as a “Type II, Style A” crate under ASTM D6039, with dimensions up to twelve-feet by four-feet by two-feet and holding up to one thousand pounds. *See* J.A. 155 tbl. 1. As relevant here, ASTM D6039 requires that those crates “shall” be built with the materials “as specified” in the standard; that both the ends and sides of the crate “shall be [made] of lumber or cleated-plywood”; and that “for gross weights exceeding 200 lb . . . exterior side cleats shall be used to facilitate fork truck handling of crates.” J.A. 156, 160–61 (ASTM D6039 §§ 6.1, 7.7.1, 7.7.4). The standard, however, does not specify if handholds can be built into a Type II, Style A crate.

At trial, Dr. Singh was questioned at length regarding whether ASTM D6039 was in fact the governing industry standard for the Container’s design. During his direct examination, Dr. Singh maintained that ASTM D6039 provided the applicable industry standard for the Container’s design, despite its sides being made of triple-wall corrugated material, because the Container’s wood ends provided the necessary “structural framework” to hold it together and “support[] the load of the product.” J.A. 453–54. On cross-examination, ODC’s counsel noted that sections 7.7.2 and 7.7.3 of ASTM D6039 required that the sides and the top members of a crate “shall” be made of lumber or pleated plywood, too. *See* J.A. 160–61. When asked if this could mean that the Container “just isn’t a wood crate,” Dr. Singh responded, “That is possible, yes, sir.” J.A. 523. The district court then inquired further:

THE COURT: [C]ould you use a container that had a wooden end and the rest of it was made of cardboard?

DR. SINGH: You can, but you still have to test it.

THE COURT: Well, okay. Would that [container] be governed by this ASTM 6039?

DR. SINGH: *It wouldn't be governed by 6039*, but there would be other testing standards that would apply. . . .

THE COURT: So it would be [alright] to [build a box with cardboard sides and wooden ends] then?

DR. SINGH: It would be [alright] to do that as long as you test it with ASTM standards.

J.A. 539–40 (emphasis added).

This final point that Dr. Singh raised—that ASTM D6039 actually did *not* apply to the Container but “there would be other testing standards that would apply,” J.A. 539—referred to what he characterized as another governing industry standard. Indeed, ASTM D6039 itself specifies that manufacturers may use other construction methods, so long as “the resulting packaging systems [are] of equal or better performance,” J.A. 154 (ASTM D6039 § 1.4), and (according to Dr. Singh) the procedure otherwise complies with ASTM D4169. But ASTM D4169 is not in the record. Most importantly, Dr. Singh never explained what sort of testing procedures ASTM D4169, or any other ASTM standards, if any, applied to the Container. And there was no testimony from Dr. Singh or anyone else as to any testing or scientific literature review done for compliance with the unidentified standards.

Despite his testimony that the Container as constructed “wouldn’t be governed by [ASTM] [D]6039,” J.A. 539, he nonetheless opined that the Container breached ASTM

D6039's requirements in two ways: (1) the handhold should not have been included in the design; and (2) the Container should have been designed with end cleats nailed vertically on the wood end pieces on the outside of the Container. ODC questioned his opinion regarding the handholds at length during cross-examination, asking him whether ASTM D6039 considered that a crate would have handholds built into it. Dr. Singh confirmed that ASTM D6039 said nothing about handholds—meaning that it did not preclude manufacturers from including them. As such, “[t]here is . . . nothing in [ASTM D6039] that refers to a [required] strength for pulling or pushing” a crate via a handhold. J.A. 525. When asked what, if any, handhold testing standards the ASTM generally required, Dr. Singh explained that they were “[i]n the ASTM book. I don’t remember that standard number off the top of my head. . . . You can search it on Google.” J.A. 542–43. And to determine how much more strength an end cleat would have added to a handhold, Dr. Singh acknowledged that “[y]ou would have to do some testing.” J.A. 526. He performed none and referenced none from any other source. And neither did any other witness.

Finally, Dr. Singh concluded that ODC’s failure to make the Container according to ASTM D6039’s specifications, and to test the Container prior to using it to ship goods, proximately caused Mr. Sardis’ death. Specifically, he opined only that if end cleats were present on the outside of the Container, the slat that Mr. Sardis pulled on “would have held more than not being present.” J.A. 546. But again, Dr. Singh did not cite to any tests that he performed on an exemplar Container or a computer-generated model, or to any other objective analysis, to reach this conclusion.

b.

Below and on appeal, ODC argues that Dr. Singh's opinions were irrelevant, because his testimony insufficiently established that ASTM D6039 was a relevant industry standard that applied to the Container. It points out that the Container is not a *wooden* crate, which is what ASTM D6039 governs. Although both ASTM D6039 crates and the Container have wooden ends, ODC asserts that the similarities end there, making ASTM D6039 an "apples-to-oranges" comparison. Opening Br. 21.

The Estate counters that the differences that ODC cites between the Container and the requirements of ASTM D6039 "prove ODC's failure to comply with the industry standard." Response Br. 15. It construes Dr. Singh's testimony as supporting the proposition that the Container's triple-wall corrugated material, when connected to the wood ends, provided the structural framework necessary to bring it within ASTM D6039's purview. Thus, the Estate contends, the jury was entitled to credit Dr. Singh's opinion that ASTM D6039 governs. We find several significant flaws in the Estate's position.

As an initial matter, whether ASTM D6039 imposed particular duties on ODC to construct the Container in a certain manner should have never been delegated to the jury. Virginia products liability law is clear that the question of whether a manufacturer has a duty to design a product in a certain manner is a question of *law* for the *court*. *Holiday Motor*, 790 S.E.2d at 454 ("Judges rather than juries determine whether the defendant was under a duty of care at all and if so what standard of care applied." (quoting 1 Dan B. Dobbs et al., *The Law of Torts* § 164 (2d ed. 2011))). The district court thus should have made this determination, not the jury. Its failure to do so was error.

Next, assuming that the court had deemed ASTM D6039 as the governing industry standard, that finding itself would constitute reversible legal error. Dr. Singh admitted during his testimony that a container made of “cardboard”—which the district court was using as shorthand for triple-wall corrugated material—“*wouldn’t be governed by [ASTM] [D]6039,*” because “[t]riple-wall corrugated [material] is not considered wood.” J.A. 538–39 (emphasis added). That admission distinguishes ASTM D6039’s requirement that a crate’s sides and ends “shall” be made of lumber or pleated plywood. *See* J.A. 156, 160 (ASTM D6039 §§ 6.1, 7.7.1–.2). Thus, based on Dr. Singh’s own testimony, ASTM D6039 could not be a governing standard for the Container. Yet he relied on it as the relevant benchmark, and the district court erroneously permitted him to do so before the jury.

The district court recognized as much during a sidebar with counsel. It noted that the Container’s mostly cardboard design lacked the interconnected interior wooden members shown in the diagrammed models in ASTM D6039 and observed, “It may be this was the wrong design to use for this [Container]. But comparing [the Container] to [ASTM D6039] *is comparing apples and oranges.*” J.A. 501 (emphasis added). Despite these obvious flaws in Dr. Singh’s testimony, the court decided to “leave [it to the parties] to fight that out” in front of the jury. J.A. 504. That decision violated both Rule 702’s gatekeeping requirement and its foundational principles of relevancy. A design standard that “does not even apply to” the product at issue categorically “lacks ‘a valid scientific connection to the pertinent inquiry.’” *Nease*, 848 F.3d at 232–33 (quoting *Daubert*, 509 U.S. at 592). It is, in simpler words, the touchstone of irrelevancy under *Daubert*.

The same logic applies to Dr. Singh's testimony regarding the propriety of the Container's handholds. While initially testifying that ASTM D6039 barred manufacturers from putting handholds on crates, Dr. Singh later admitted that ASTM D6039 said nothing one way or the other about handholds:

ODC'S COUNSEL: I want to be clear, I am not trying to play semantics, there is nothing in ASTM D 6039 for any of the styles or types . . . of crates in there that has anything [to] do with manual handles, or hand holds by any other name, anywhere in the standard; right?

DR. SINGH: Nothing referred to handles or hand holds in [ASTM] D 6039.

ODC'S COUNSEL: In fact [ASTM] D 6039 doesn't even contemplate an option for a hand hold in an all-wood crate?

DR. SINGH: That is correct.

J.A. 524. An industry standard that says nothing about the propriety of handholds—and ergo, nothing about how those handholds should be tested (if they need to be tested at all)—is not relevant to the Estate's claims or helpful to the jury's breach determination.

Lastly, at first blush, Dr. Singh's testimony that the ASTM requires manufacturers to test a product that deviates from ASTM D6039's requirements appears relevant. But in reality, Dr. Singh never explained what those testing standards are or if they even exist. Instead, Dr. Singh pointed the district court and the jury to "Google" for standards he could not identify. J.A. 542–43. No other witness offered testimony on these unidentified standards. That is patently insufficient to establish a duty to test a product in a certain way and a breach of that duty. The expert must be able to identify and explain those industry

testing standards and why the product in question met or failed that test. Without such evidence, the jury here could not properly ascertain whether ODC breached an unidentified industry standard and was forced to speculate a guess because all that the jury had to verify that the industry requires testing is Dr. Singh's vague *ipse dixit*. That cannot satisfy Rule 702.⁴ See *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (“[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.”); *Daubert*, 509 U.S. at 590 (“‘[K]nowledge’ connotes more than subjective belief or unsupported speculation.”); see also Fed. R. Evid. 702 advisory committee’s note to 2000 amendments (“The trial court’s gatekeeping function requires more than simply ‘taking the expert’s word for it.’”).

In sum, the district court committed legal error in failing to strike Dr. Singh’s testimony under *Daubert* as irrelevant, because his testimony failed to establish an industry standard governing the Container, much less a breach of that alleged standard.

c.

ODC also challenged Dr. Singh’s opinion on proximate causation as unreliable, arguing that under our decision in *Nease*, Dr. Singh’s failure to test any exemplar or representative Container rendered his opinion unreliable. According to ODC, even if

⁴ The Estate also points to Dr. Singh’s reliance on Chapter Four of the *Handbook of Paper and Wood Packaging Technology* as a relevant industry standard. That treatise provides that placing cleats on the *inside* of a wooden crate (which the Container here did) “reduces the carrying capacity to less than 200 pounds.” J.A. 475. Dr. Singh never explained, however, how a reduction in carrying capacity would reduce the strength of handholds on the *outside* of a container. So even assuming that this is an industry standard, it is irrelevant to the handhold discussion.

ASTM D6039 gave some insight into how much pull resistance handholds would have with end cleats on the outside, “it would not help [the Estate] here, since Dr. Singh did not do any kind of analysis to see how much force Mr. Sardis actually applied on the Container or how much force a container with exterior end cleats would have held.” Opening Br. 50.

The Estate attempts to distinguish *Nease* by arguing that the expert there “sought to extrapolate data relating to one model of truck to another model,” while here Dr. Singh testified as to “a product’s demonstrated failure to meet established safety standards.” Response Br. 28. Thus, the Estate contends, given Dr. Singh’s extensive credentials and “unchallenged expertise,” his testimony satisfied *Daubert* and Rule 702. *Id.* On this point, too, ODC’s argument finds stronger support in our precedent.⁵

At trial, Dr. Singh testified only in a summary fashion that the lack of vertical end cleats on the Container’s wooden ends, and ODC’s failure to test the handholds prior to placing the Container in the stream of commerce, proximately caused Mr. Sardis’ death. His only explanation of the former proposition was to opine that end cleats “would have held [the handhold slat] more than not being present.” J.A. 546.

For an expert opinion to be reliable, it must be “based on scientific, technical, or other specialized *knowledge* and not on belief or speculation.” *Nease*, 848 F.3d at 229

⁵ During oral argument, the Estate asserted that ODC waived any challenge to Dr. Singh’s proximate causation opinion by failing to object to it when Dr. Singh offered it at trial. *See also* Response Br. 17. We disagree. ODC properly preserved this issue for appeal by filing a motion in limine specifically requesting, *inter alia*, that the district court exclude Dr. Singh’s proximate causation opinion at trial under *Daubert*, which the district court denied. *See United States v. Williams*, 81 F.3d 1321, 1325 (4th Cir. 1996).

(citation omitted). “One especially important factor for guiding a court in its reliability determination is whether a given theory has been tested.” *Id.* at 231. While a lack of testing is not dispositive, *id.* at 232, we have nonetheless recognized that “a plaintiff may not prevail in a products liability case by relying on the opinion of an expert unsupported by any evidence such as test data or relevant literature in the field,” *Oglesby*, 190 F.3d at 249 (citation omitted). Thus, in cases such as this one, whether the proffered expert’s theory has been, or can be, tested or otherwise proved objectively will ordinarily be a “key question to be answered” in the judge’s reliability analysis. *Daubert*, 509 U.S. at 593.

Dr. Singh’s opinions, as far as they go, are “scientific” in nature. *See* Fed. R. Evid. 702; *Daubert*, 509 U.S. at 590. They “raise basic, testable engineering concepts governing how an object will perform when subjected to certain forces.” Brief for Prod. Liab. Advisory Council, Inc. as Amicus Curiae Supporting Appellant 14. So “[t]esting was of critical importance in this case,” *Nease*, 848 F.3d at 231, in order to ensure that Dr. Singh’s opinion was based on scientific *knowledge*. After all, “to qualify as ‘scientific knowledge,’ an inference or assertion must be derived by the scientific method.” *Daubert*, 509 U.S. at 590. Dr. Singh admitted as much, testifying that to determine how strong the Container’s handhold was or how much more strength vertical end cleats would provide, “[y]ou would have to do some testing.” J.A. 526.

Dr. Singh, “however, conducted no testing whatsoever to arrive at his opinion.” *Nease*, 848 F.3d at 232. Despite the actual Container at issue being unavailable, Dr. Singh made no efforts to create a computer-generated or physical model of the Container, and the Estate turned down ODC’s offer to construct three exemplars of the Container. Without

such testing, Dr. Singh could not competently respond to several questions that required answers in order to reliably arrive at his ultimate proximate causation opinions. Regarding the failure to test the handhold, Dr. Singh did not describe (a) what sort of pull-strength resistance the packaging industry requires handholds to withstand, and (b) whether the Container's handholds met those pull-strength resistance requirements. After all, a failure to test could not have proximately caused Mr. Sardis' death if the Container's handholds would have satisfied the industry's standards. And regarding the alleged need for end cleats, several more questions remain unanswered: (a) Since ASTM D6039 does not speak to handholds, were end cleats necessary to bring the Container's handholds within the industry standard for pull-strength resistance?; (b) If so, would end cleats have in fact given the Container's handholds the required pull-strength resistance?; and (c) Perhaps most importantly, had ODC included end cleats on the Container's wooden ends, would the amount of force Mr. Sardis used to pull on the Container's handhold still have exceeded the handhold's increased pull-strength resistance? It is certainly possible that Mr. Sardis pulled with such force that "industry standard" end cleats would not have prevented the handhold from breaking. Dr. Singh made no effort to consider any of these relevant factors and neither did any of the Estate's other witnesses.

Just as in *Nease*, "[Dr. Singh's] failure to test his hypothes[es] renders his opinions on the cause of [Mr. Sardis'] accident unreliable." 848 F.3d at 232. While his "theory is plausible and 'may even be right, it is no more than a hypothesis, and it thus is not knowledge, nor is it based upon sufficient facts or data or the product of reliable principles and methods applied reliably to the facts of the case.'" *Id.* (alterations and citation omitted).

The other *Daubert* guideposts for reliability confirm this point. Dr. Singh employed no identified methodology to reach his conclusion about the handhold slat breaking in this case, or his conclusion that testing the handhold would have established its noncompliance with the alleged industry standards, so “it would hardly be possible to solicit peer review.” *Id.* Nor would it be possible for another expert to recreate and test Dr. Singh’s theories for the potential rate of error. *Id.* His opinions are therefore unreliable.

The Estate and the district court appear to rely solely on ASTM D6039 as remedying these defects. The district court first found that Dr. Singh’s opinions were admissible despite his lack of testing because “where an expert is otherwise qualified to testify, a lack of testing or failure to identify industry standards affects the weight of the evidence.” J.A. 1179 (quoting *Bilenky v. Ryobi Ltd.*, No. 2:13cv345, 2014 WL 7530365, at *4 (E.D. Va. Dec. 5, 2014)); accord J.A. 289. Second, the court pointed out, Dr. Singh relied on an industry standard, ASTM D6039, distinguishing his opinions from those in *Nease*. Both points are unpersuasive.

First, the district court’s reliance on *Bilenky*, an unpublished decision, is misplaced. Unlike *Bilenky* and the district court here, we do not read *Alevromagiros v. Hechinger Co.*, 993 F.2d 417 (4th Cir. 1993), to stand for the proposition that a lack of testing and/or a failure to identify industry standards can never render an expert’s testimony inadmissible at the *Daubert* gate. In fact, *Alevromagiros* never considered a Rule 702 challenge; it merely considered whether the expert testimony admitted at trial sufficiently proved a design defect under Virginia law. See 993 F.2d at 420–21. And even if *Alevromagiros* stood for the rule that *Bilenky* and the district court here attributed to it, we would reject it.

Alevromagiros preceded the Supreme Court’s decision in *Daubert*, the latter of which made clear that testing and a failure to cite industry standards can impact an expert opinion’s reliability, one of the two preconditions for admissibility. Had the district court assured itself that Dr. Singh’s opinions were reliable at the *Daubert* gate, then a lack of testing and/or a failure to identify industry standards might have only impacted the weight of his testimony. That was not the case here, as the district court failed to make those threshold relevancy and reliability determinations.

Second, Dr. Singh’s reliance on ASTM D6039 cannot, as the district court appeared to intimate, serve as a proxy for testing. Setting aside the fact that ASTM D6039 is an irrelevant standard—which by itself is fatal to this argument—Dr. Singh admitted during trial that “we can’t find out . . . how much strength an end cleat has to keep slats from pulling out” by looking only at ASTM D6039. J.A. 526. Instead, “[y]ou would have to do some testing.” *Id.* (emphasis added). Nor does ASTM D6039 “refer[] to a [handhold] strength for pulling or pushing” generally. J.A. 525. So assuming that an industry standard could serve as a “proxy” for testing, *see Nease*, 848 F.3d at 233, ASTM D6039 is not such a standard by Dr. Singh’s own admission.

All of this to say: even if an expert provides relevant testimony as to how an allegedly defective product breached a governing industry standard (which Dr. Singh did not do here), that says nothing about whether the expert reliably opined that said breach *caused* a plaintiff’s harm. There must be some objective basis to satisfy the district court that the conclusion reached was the product of reliable principles and methods. “Without testing, supporting literature in the pertinent field, peer reviewed publications[,] or some

basis to assess the level of reliability, expert opinion testimony can easily, but improperly, devolve into nothing more than proclaiming an opinion is true “because I say so.” *Small v. WellDyne, Inc.*, 927 F.3d 169, 177 (4th Cir. 2019). That is precisely what occurred here with Dr. Singh. The district court thus abused its discretion by allowing the jury to receive Dr. Singh’s *ipse dixit* opinion. *See Joiner*, 522 U.S. at 146.

3.

We now turn to ODC’s relevance and reliability challenges to Dr. Wogalter’s testimony, pausing first to provide a brief overview of the substance of his testimony.

a.

Dr. Wogalter was the Estate’s only expert to testify in support of its failure to warn claim. He described himself as an expert on “human factors,” which he described as “a discipline of study that deals with the design of products and systems based on people’s abilities and limitations to promote productivity, satisfaction, and safety.” J.A. 96, 555.

First, Dr. Wogalter testified that manufacturers have a duty to conduct a “hazard analysis” of a product, which entails considering how a product will be used at “all different stages” of its “life cycle.” J.A. 562. He opined that a proper hazard analysis entails “solicit[ing] feedback,” instead of “just wait[ing]” to hear of problems. J.A. 564. The district court questioned Dr. Wogalter about how ODC would have discovered that the handhold was dangerous, because his testimony “[was] kind of vague.” J.A. 573. Dr. Wogalter responded that ODC would have discovered this by performing additional, but unidentified, testing, as well as “go[ing] out and talk[ing] to people” to see “how they use [the Container],” see “how they move [it] around,” and “try to figure out what is going to

happen to [the handhold] out in the field.” J.A. 577. Had they done this and further testing, he testified that ODC “would have found problems that the slat could come off from pulling on it.” J.A. 569. He admitted, however, that there is no existing literature on how to test human factors “that [he] know[s] of,” because “it is a general technique that cuts across products.” J.A. 574. And, he conceded that he never engaged in his own hazard analysis of any facsimile of the Container or anything comparable to it.

Second, given the handhold’s alleged dangers, Dr. Wogalter opined that some warning system was necessary. He described the general types of information that are typically contained in generic warnings, how those warnings are fashioned onto packaging, and to whom that information is distributed. However, Dr. Wogalter did not proffer what specific warnings should have been placed on the Container.

Third, despite not having opined as to what particular warnings should have been placed on the Container, Dr. Wogalter concluded that the failure to conduct a hazard analysis, and to include any warnings, proximately caused Mr. Sardis’ death. He stated that “there is plenty of research that . . . warnings are effective, and that certainly it is better than no warning,” but never explained what that research was, or why Mr. Sardis would have heeded those warnings. J.A. 585.

b.

ODC first argued in its motion in limine, and again in its post-trial Rule 50(b) motion, that Dr. Wogalter’s testimony was contrary to the Virginia standard for failure to warn claims. Reiterating those arguments on appeal, ODC asserts that Dr. Wogalter’s testimony was premised on what ODC *should* have done to discover any potential dangers

associated with the Container's handholds. But ODC posits that settled Virginia law only imposes liability upon a manufacturer if it had a *reason* to know of the danger. For that reason, ODC argued, Dr. Wogalter's testimony on an alleged duty to warn was irrelevant.

The Estate and the district court adopted the view that Virginia's duty to warn case law focuses on the notion "that the manufacturer should have superior knowledge of his product." Response Br. 29 (citation omitted). And Dr. Wogalter testified that ODC failed to maintain such superior knowledge by "bury[ing] its head in the sand" and failing to consider any potential dangers. *Id.* (quoting J.A. 1185). But this logic rests on a flawed application of Virginia's failure to warn jurisprudence. The proper application, which ODC presents, compels the conclusion that Dr. Wogalter's testimony was irrelevant.

Part of a plaintiff's burden in failure to warn cases under Virginia law is to show that the manufacturer "knows or has reason to know that the [product] is or is likely to be dangerous for the use for which it is supplied." *Featherall*, 252 S.E.2d at 366 (quoting Restatement (Second) of Torts § 388 (Am. Law Inst. 1965)). The Supreme Court of Virginia has spoken at length about this standard, emphasizing that "[t]here is a significant legal difference between the phrases *reason to know* and *should know*":

The words "reason to know" . . . denote the fact that the actor has information from which a person of reasonable intelligence or of the superior intelligence of the actor would infer that the fact in question exists, or that such person would govern his conduct upon the assumption that such fact exists.

The words "should know" . . . denote the fact that a person of reasonable prudence and intelligence or of the superior intelligence of the actor would ascertain the fact in question in the performance of his duty to another, or would govern his conduct upon the assumption that such fact exists.

Owens-Corning Fiberglass Corp. v. Watson, 413 S.E.2d 630, 634–35 (Va. 1992) (enumeration omitted) (quoting Restatement (Second) of Torts § 12). In other words, “‘reason to know’ implies no duty of knowledge,” but “‘should know’ implies that the actor owes another the duty of ascertaining the fact in question[] . . . and that he would ascertain the existence thereof in the proper performance of that duty.” *Id.* at 635 (quoting Restatement (Second) of Torts § 12 cmt. a).

Dr. Wogalter’s testimony is incompatible with the governing Virginia “reason to know” standard. As *Watson* shows, Dr. Wogalter’s testimony needed to focus on whether the field testing ODC performed, and the other institutional knowledge within ODC’s purview, like the feedback from its customers about containers, had caused ODC to learn—or otherwise gave them reason to know—that the wooden handholds would fail when pulled with a certain level of force. *Id.* at 634–35 (holding that the trial court’s instructions that a defendant had “a duty to ascertain and ‘keep informed’ of scientific facts” “imposed an inappropriate standard” under Virginia law, but nonetheless upholding the verdict because the defendant failed to object to the instructions, so they became the law of the case); *see also Torkie-Tork v. Wyeth*, 757 F. Supp. 2d 567, 572–73 (E.D. Va. 2010) (excluding expert testimony that a company should have tested its pharmaceutical drug more, because the duty to warn in Virginia is only based on “those dangers which [the defendant] knew or had reason to know existed based on the science available at the time the product left [its] hands”).

But that is not the testimony that Dr. Wogalter provided. He did not explain how or why, based on the facts reasonably available to ODC, its “superior knowledge” would have

caused it to infer that the Container’s handhold had any inherent danger. *See Watson*, 413 S.E.2d at 634. Instead, he merely speculated as to *how* ODC should have gone about discovering if such a condition was present. Specifically, his testimony regarding the need to conduct a hazard analysis was premised on ODC’s alleged need to *ascertain* whether the Container’s handholds would break when pulled on in the field. *See, e.g.*, J.A. 561 (“Hazard analysis, at least the goal of it, is to determine what hazards are potential with the product.”). And his ultimate opinion was that if ODC had performed a hazard analysis (which Dr. Wogalter failed to describe), “[it] would have *found* problems that the [handhold] slat could come off from pulling on it.” J.A. 569 (emphasis added). Stated differently, Dr. Wogalter testified about what ODC *should* have known. That genre of testimony is incompatible with Virginia law, *see Watson*, 413 S.E.2d at 634–35, and should have been excluded as irrelevant, *see Daubert*, 509 U.S. at 591 (“Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.” (citation omitted)).⁶

⁶ Had Dr. Wogalter grounded his testimony in an industry standard (which, assuming it exists, he never identified) governing the testing of container handholds, then his theory may have relevance because that could show inadequacies in ODC’s field testing of the Container design and how it failed to maintain superior knowledge of its product. But Dr. Wogalter never once pointed to an industry standard governing the testing of handholds. In fact, he admitted that there is no existing literature on how to test human factors generally. Without that foundation, his testimony is nothing more than his mere *ipse dixit*, his speculative guess, about what ODC should have done in hindsight. Thus, we need not consider whether Virginia law would contemplate a manufacturer being held liable for a failure to warn under a “bury its head in the sand” line of reasoning.

c.

Assuming *arguendo* that Dr. Wogalter’s hazard analysis testimony was relevant, we would nonetheless conclude that the district court abused its discretion in finding his ultimate conclusions reliable.

None of the *Daubert* hallmarks of reliability—testing, peer review, literature, rate of error, or general acceptance—are present in Dr. Wogalter’s testimony that an undefined hazard analysis would have uncovered the alleged dangers in the Container’s design. First, as to testing, Dr. Wogalter admitted that he did not develop a hazard analysis protocol that would be proper for the Container in this case. He admitted that he did not perform a hazard analysis of an exemplar Container or any computer modeled facsimile. He could not recite a hazard analysis he or anyone else performed in an analogous context that would apply to the Container. And he admitted that he “[was] not familiar with all the ways that [the Container] is even handled,” because, in his words, “I don’t have access to stuff that you [ODC’s counsel] are saying I should have.” J.A. 595. Just as in *Nease*, Dr. Wogalter “presented a hypothesis only,” but “failed to validate it with testing” or any other objective comparison, which “renders his opinions . . . unreliable.” 848 F.3d at 232.

Again, the other *Daubert* reliability guideposts confirm this point. Dr. Wogalter utilized no specified methodology, so his theories could not have been subject to peer review. In fact, he conceded that there is no existing literature on how to test human factors “that [he] know[s] of.” J.A. 574. He also confirmed that it is not general knowledge that part of a hazard analysis for garage door hood containers is “a pulling test” to determine pull-strength resistance. J.A. 571–72. Nor could Dr. Wogalter describe any other prior case

in which he, or any other expert, conducted a hazard analysis on a similar container that also involved an allegedly defective handhold. Nowhere in his testimony did he offer any facts, test data, or peer-reviewed literature for reaching his conclusion.⁷ Thus, it was impossible for the district court, and impossible for us on appeal, to ascertain the potential rate of error in Dr. Wogalter's hazard analysis approach and whether hazard analyses are widely accepted in the field of "human factors."

The district court recognized as much when it engaged in its own extensive questioning of Dr. Wogalter. It attempted to pinpoint a basis for Dr. Wogalter's proposed hazard analysis because, in the court's own words,

you [Dr. Wogalter] haven't even given us an example of this happening in the real world other than your thought that this is something that they ought to have done. *What you have given us is kind of vague.* . . . So I sort of would like to know how this process works in a little more detail so that we can figure out whether there is a likelihood of good results. I haven't heard that. Maybe I am just missing something.

J.A. 573 (emphasis added). The district court, in fact, was not missing anything. Dr. Wogalter simply offered only his *ipse dixit* in support of his opinions. This is the hallmark of an unreliable opinion. *See, e.g., Oglesby*, 190 F.3d at 250. It was therefore an abuse of discretion to allow the jury to hear this testimony. *See Nease*, 848 F.3d at 232.

⁷ Dr. Wogalter also cited Dr. Singh's testimony, explaining that ODC's hazard analysis was insufficient because it failed to conduct "a pulling test." J.A. 571–72. But as noted above, Dr. Singh's testimony failed to reliably demonstrate how this would have shown that the Container was defectively designed. Dr. Wogalter's inability to explain this point only confirms the unreliability of this portion of his testimony.

The same deficits are present in his conclusions regarding the need for warnings. He testified that to abate the hazards inherent in the Container's handholds, ODC had to give "appropriate warnings . . . whatever they might be. And there is a whole literature on how to make proper warnings[.]" J.A. 577. But, he admitted, he did not "determine[] the exact language" that should have been included in the warnings. J.A. 583. He nonetheless opined that the lack of an unspecified warning proximately caused Mr. Sardis' death. He pointed to no peer-reviewed literature, test data, or any other facts to support his claim that an unspecified warning placed on the Container would have been heeded by Mr. Sardis. Again, all that supported Dr. Wogalter's opinions was his own *ipse dixit*. Thus, just as with Dr. Singh, it was an abuse of discretion to admit this testimony into evidence. *See Nease*, 848 F.3d at 232; *Oglesby*, 190 F.3d at 250. The jury should not have been permitted to hear any of Dr. Wogalter's unverified and *ipse dixit* opinions.

* * * *

Because Drs. Singh and Wogalter provided irrelevant and unreliable testimony as a matter of law, we hold that the district court necessarily committed harmful error when it abdicated its critical *Daubert* gatekeeping function both at the motion in limine and Rule 50(b) stages. With that inadmissible expert testimony excised from our own consideration, we turn our attention to whether the remaining admissible evidence could support the jury's verdict.

IV.

Even without Drs. Singh's and Wogalter's testimony, the Estate contends that ODC is not entitled to judgment as a matter of law. It asserts that the lay witness testimony offered at trial, largely from ODC's corporate designee, was sufficient to establish both that the Container was defectively designed, and that ODC breached its duty to warn consumers of the dangers inherent in the Container's handholds. Both contentions fail.

A.

The Estate first argues that it sufficiently demonstrated that the Container was defectively designed through the consumer expectations test. It points to the testimony of ODC's corporate designee, Mr. Knable, who "agree[d]" that users "can reasonably expect that if they pull on [the Container's handhold] that it will hold up[.]" J.A. 1372. Taking this statement in the light most favorable to the Estate still does not establish a design defect.

Under Virginia law, a design defect can be shown if a product fails to conform with "reasonable consumer expectations"—"those expectations [that] reveal how society 'balances known risks and dangers [inherent in a product design] against the feasibility and practicability of applying any given technology' to enhance product safety." *Redman v. John D. Brush & Co.*, 111 F.3d 1174, 1181 (4th Cir. 1997) (second alteration in original) (citation omitted). Consumer expectations can be shown by direct evidence, "published literature" (which includes sources like "marketing, advertising, presentation, promotional materials, product manuals, and instruction booklets"), and "industry practices recognizing a safety standard that reasonable consumers expected." *Evans*, 810 S.E.2d at 470. The necessary focus on *reasonable* consumer expectations means that "wholly subjective

expectations are insufficient to establish the degree of protection reasonable consumers expect from a product.” *Id.* (citing *Redman*, 111 F.3d at 1181).

Our *Redman* decision is instructive. There, the plaintiff sought to establish that a safe marketed as “burglar-deterrent” was defectively designed, because a reasonable consumer “would have expected the particular safe [the plaintiff] purchased to provide more burglary protection than it did.” 111 F.3d at 1181. We held that the plaintiff’s evidence—which consisted only of his own self-serving statements that the safe was “marketed as ‘burglar-deterrent’” and “would provide ‘a degree of protection against burglary’”—was insufficient to establish what a reasonable consumer expected of the safe. *Id.* Besides the subjective nature of this evidence, we faulted the plaintiff for failing to “establish *how much* burglary protection reasonable consumers would expect from a burglar-deterrent safe.” *Id.* (emphasis added).

Similarly, here, Mr. Knable’s statement fails to establish a reasonable consumer’s expectations as to how much pull-strength resistance would apply to the Container’s handhold. Any consumer (i.e., an ODC distributor’s employee handling a Container) would expect the handhold to “hold up” when pulled. But just as in *Redman*, the Estate was required, but failed, to “establish *how much* [pull-strength resistance] reasonable consumers would expect.” *Id.* (emphasis added). Moreover, the Estate provided *no* admissible evidence on the issue of proximate causation. It failed to demonstrate (1) that the force that Mr. Sardis used in pulling on the Container’s handhold fell within a consumer’s expected metric, or (2) that with the proposed modification (end cleats), the Container’s handhold here would not have failed based on the force used. The fact that a

handhold may have failed on one occasion does not establish reasonable consumer expectations. In short, apart from the metaphysical speculation of a handhold that sustains an unidentified quantum force, the Estate offered *no* evidence to quantify any expectation of force resistance.

Accordingly, without Dr. Singh's inadmissible expert testimony, the Estate failed to meet its burden of proof on its design defect claim.

B.

Next, the Estate asserts that its failure to warn claim survives without Dr. Wogalter's expert testimony. In support, it points to four alleged admissions that ODC made during trial: (1) that ODC has an "obligation to [e]nsure that its products that it designs and manufactures comply with industry standards," J.A. 794–95; (2) that industry standards exist "[t]o protect people," J.A. 1298; (3) that "ODC shouldn't sell or distribute a product that does not comply with applicable industry standards," J.A. 1298–99; and (4) that "one of the ways people can be injured or killed is if [ODC] sells or distributes a product that does not comply with applicable industry standards," J.A. 1299. This testimony, the Estate posits, "provided ample grounds for the jury to conclude that the company had reason to know of the [Container's] potential dangers." Response Br. 23. Even when reading these statements in the light most favorable to the Estate, we disagree.

In order for these statements to support the jury's finding that ODC had a duty to warn of the dangers allegedly posed by the Container's handholds, we must discern some evidence that ODC knew or had reason to know of those dangers. *See Watson*, 413 S.E.2d at 634; *Featherall*, 252 S.E.2d at 366–67. For argument's sake, we will assume that the

statements the Estate points to establish that ODC would have a duty to warn of the dangers that the Container's handholds posed if its design breached industry standards. But that is as far as these statements could take the Estate, for they fail to establish that ODC actually breached such a duty. With Drs. Singh's and Wogalter's testimony excluded, there are no facts establishing how ODC knew, or how its exercise of reasonable prudence would have given it reason to know, that the handholds violated some industry standard.

The district court found that ODC breached its duty to warn by "bury[ing] its head in the sand" to the handhold's potential dangers, J.A. 1185 (citation omitted), based on Mr. Knable's testimony that ODC "[n]ever consider[ed] the potential dangers that its packaging or crates can pose to others," J.A. 1297. Assuming that this theory of breach is compatible with Virginia law—and that the Estate sufficiently proved it—the Estate nonetheless failed to prove causation as a matter of law.

The burden of establishing that ODC's breach of a duty to warn proximately caused Mr. Sardis' injuries lies with the Estate. *See, e.g., Robey v. Richmond Coca-Cola Bottling Works*, 64 S.E.2d 723, 726 (Va. 1951). As a matter of Virginia law, "before submitting [the issue of proximate causation] to a jury," the plaintiff must provide "[e]vidence tending to show a causal connection . . . sufficient to remove the case out of the realm of speculation and conjecture and into the realm of legitimate inference." *Phillips v. Se. 4-H Educ. Ctr., Inc.*, 510 S.E.2d 458, 461 (Va. 1999) (citation omitted). There is no admissible record evidence in this case bringing the proximate causation issue "into the realm of legitimate inference." *Id.* ODC's failure to conduct an unidentified level of testing on the Container's handholds gives the jury no factual basis to conclude, let alone infer, that had ODC done

such testing, it would have discovered the dangers that the Estate claims are inherent in it. For example, the handhold may have fallen below industry standards for pull-strength resistance (assuming such standards exist), but on this record, it is just as likely that the handhold met or exceeded these alleged standards. With no evidence either way, all that the jury could do was speculate. That is plainly insufficient to support a jury verdict under Virginia law. *See id.* (holding that testimony that the decedent would have had a “good chance” of recovery had artificial respiration been undertaken sooner failed to “remove[] the issue of causation from the realm of speculation and conjecture”).

In sum, without Drs. Singh and Wogalter, the Estate did not prove that ODC had a duty to warn, that it breached that duty to warn, or that such a breach proximately caused Mr. Sardis’ injuries. Its failure to warn claim therefore fails as a matter of law.

C.

Given our holdings above regarding the Estate’s evidentiary failures on its design defect and failure to warn claims, ODC’s arguments pertaining to the general negligence and breach of the implied warranty of merchantability claims may be addressed in relatively short order. As noted at the outset, Virginia law imposes identical requirements for products liability claims brought under both negligence and breach of the implied warranty of merchantability theories. *Evans*, 810 S.E.2d at 469. One of those necessary elements is that the product “w[as] unreasonably dangerous,” which in turn requires showing that the product was “defective in assembly or manufacture, unreasonably dangerous in design, or unaccompanied by adequate warnings concerning its hazardous properties.” *Id.* (citations omitted). The Estate, however, has failed to prove any design

defect or failure to warn. Accordingly, on this ground alone, we must hold that the Estate failed to carry its burden on these final two claims for relief.⁸

D.

The final matter for our consideration is whether we should remand this case for a new trial, remand for the district court to assess whether a new trial is proper, or direct that judgment be entered for ODC as a matter of law. *See* Fed. R. Civ. P. 50(e). One of the “key[s] to [our] exercise of . . . discretion” in this analysis is “fairness to the parties.” *Weisgram*, 528 U.S. at 454. With great respect for the jury’s role in our adversarial system, the circumstances of this case and the equitable considerations of fairness to both parties counsel us to direct the district court to enter judgment as a matter of law in ODC’s favor.

Writing for the unanimous *Weisgram* Court, Justice Ginsburg observed that “[s]ince *Daubert*, . . . parties relying on expert evidence have had notice of the exacting standards of reliability such evidence must meet.” *Id.* at 455. So it is fair to enter judgment as a matter of law for the losing party below when the appellate court finds the prevailing party’s expert testimony inadmissible on appeal, because “[i]t is implausible to suggest, post-*Daubert*, that parties will initially present less than their best expert evidence in the expectation of a second chance should their first try fail.” *Id.* at 455–56. That fairness is only amplified in a case like this, where “[the Estate] was on notice every step of the way that [ODC] was challenging [its] experts, [and it] made no attempt to add or substitute other

⁸ Given these holdings, we need not address ODC’s remaining contentions that the district court erred in formulating the verdict form and a number of the jury instructions.

evidence.” *Id.* at 456. As in *Weisgram*, the Estate has “offered no specific grounds for a new trial”; it only asserts that the evidence it presented below was sufficient to support the verdict entered in its favor. *Id.* Given the near identical overlap between the circumstances of this case and that in *Weisgram*, we elect to follow the path already cleared by the Supreme Court, and direct that judgment as a matter of law be entered in ODC’s favor as to all of the Estate’s claims for relief.

V.

For the foregoing reasons, we reverse the judgment of the district court and remand this case with instructions for the district court to enter final judgment in ODC’s favor.

REVERSED AND REMANDED WITH INSTRUCTIONS

**ADVISORY COMMITTEE
ON
EVIDENCE RULES**

April 30, 2021

ADVISORY COMMITTEE ON EVIDENCE RULES

AGENDA FOR COMMITTEE MEETING

April 30, 2021

I. Committee Meeting --- Opening Business

Opening business includes:

- Introduction of new members, Hon. Richard Sullivan and Arun Subramanian, Esq.
- Approval of the minutes of the Fall, 2020 meeting.
- Report on the January, 2021 meeting of the Standing Committee.

II. Rule 702

The Committee has been considering two possible changes to Rule 702: 1) an amendment regulating overstatement of expert conclusions --- or instead a compromise that focuses the court on the expert's opinion in considering whether the expert's method was reliably applied and sufficiently based on facts or data; and 2) an amendment providing that the admissibility requirements set forth in the rule --- most especially sufficiency of basis and reliability of application --- are matters that must be decided by the court by a preponderance of the evidence under Rule 104(a). The memorandum prepared by the Reporter and Professor Richter on these possible changes is behind Tab 2.

Immediately behind the memorandum are two attachments:

1. A case digest prepared by the Reporter on forensic expert testimony; and
2. Letters and Reports to the Committee from members of the public regarding an amendment to Rule 702.

III. Rule 106

The Committee has been considering a proposal to amend Rule 106, the rule of completeness, for two purposes: 1. to specify that completing evidence is admissible over a hearsay objection; and 2. to extend its coverage to oral statements. The Reporter's memorandum on the subject is behind Tab 3.

III. Report on June 2020 Standing Committee Meeting

The Reporter gave a report on the June 2020 meeting of the Standing Committee. He reminded the Committee that the Evidence Advisory Committee presented no action items at the June meeting. The Reporter and Judge Livingston informed the Standing Committee on the Committee's continuing work on Rules 106, 615, and 702. They also reported on the potential need for an "emergency" evidence rule pursuant to the CARES Act that would enable the suspension of certain evidence rules during an emergency (such as the covid-19 pandemic). Based upon their careful research and review, they reported that there was no need for an emergency evidence rule. The Reporter noted that he had included a memorandum regarding the emergency rule issue in the Agenda materials and that the Committee would be given an opportunity to provide input on the issue later in the meeting.

IV. Potential Amendment to FRE 702

The Chair opened the substantive agenda with a discussion of FRE 702. He noted that the Committee had been considering two potential amendments to FRE 702 for the past few years: 1) an amendment that would clarify the application of the FRE 104(a) preponderance standard of admissibility to FRE 702 inquiries and 2) an amendment that would prevent an expert from "overstating" her conclusions. The Chair proposed to discuss each potential amendment in turn, noting that no votes would be taken at the meeting. He explained that the goal of the discussion would be to narrow amendment alternatives and to have a proposal that could be voted upon at the Spring 2021 meeting.

A. Amending FRE 702 to Clarify the Application of FRE 104(a)

The Reporter reminded the Committee that the FRE 104(a) issue came to the Committee's attention through a law review article by David Bernstein & Eric Lasker. The Reporter's research --- as well as research provided by a number of parties who had submitted comments to the Committee --- reveals a number of federal cases in which judges did not apply the preponderance standard of admissibility to the requirements of sufficiency of basis and reliable application of principles and methods, instead holding that such issues were ones of weight for the jury. In other cases, the Reporter noted wayward language by federal courts suggesting that FRE 702 inquiries were ones of weight, even where the judge appeared to apply the appropriate FRE 104(a) standard. The Reporter noted that based on the discussion at previous meetings, all Committee members were in agreement that the FRE 104(a) preponderance standard applies to a trial judge's admissibility findings under FRE 702, and that courts should state that they are applying that standard.

The Committee has been considering an amendment to FRE 702 to expressly provide that the trial judge must find the requirements of the Rule satisfied by a preponderance of the evidence. The Reporter noted that one concern about such an amendment might be that FRE 104(a) already applies to FRE 702 under existing rules. Indeed, he noted that express preponderance language likely would have been rejected in 2000 when Rule 702 was amended to reflect the *Daubert* opinion *because* the preponderance standard was already baked into the existing Rule. Twenty

III. Drafts of a Possible Amendment to Rule 702

1. Draft One --- Amendment Modifying 702(d) and Adding 104(a) language to rule text

Rule 702. Testimony by Expert Witnesses

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the court finds that the proponent has demonstrated by a preponderance of the evidence that:

- (a) the ~~expert's~~ witness's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the ~~expert- witness's~~ has reliably applied opinion is limited to what may be drawn from reliably applying the principles and methods to the facts of the case or data.

Draft Committee Note

Rule 702 has been amended in two respects. First, the Rule has been amended to clarify and emphasize that the admissibility requirements set forth in the Rule must be established to the court by a preponderance of the evidence. *See* Rule 104(a). Of course, the Rule 104(a) standard applies to most of the admissibility requirements set forth in the Evidence Rules. *See Bourjaily v. United States*, 483 U.S. 171 (1987). But unfortunately many courts have held that the critical questions of the sufficiency of an expert's basis, and the application of the expert's methodology, are generally questions of weight and not admissibility. These rulings are an incorrect application of Rules 702 and 104(a) and are rejected by this amendment.

There is no intent to raise any negative inference regarding the applicability of the Rule 104(a) standard of proof for other rules. The Committee concluded that emphasizing the preponderance standard in Rule 702 specifically was made necessary by the courts that have ignored it when applying the reliability requirements of that Rule.

The amendment clarifies that the preponderance standard applies to the three reliability-based requirements added in 2000. But of course other admissibility requirements in the rule ---

such as that the expert must be qualified --- are governed by the Rule 104(a) standard as well. The amendment focuses on subdivisions (b)-(d) because those are the requirements that many courts have incorrectly determined to be governed by the more permissive Rule 104(b) standard.

Of course, some challenges to expert testimony will raise matters of weight rather than admissibility even under the Rule 104(a) standard. For example, if the court finds by a preponderance of the evidence that an expert has relied on sufficient studies to support an opinion, the fact that the expert has not read every single study that exists will raise a question of weight and not admissibility. But this does not mean, as certain courts have held, that arguments about the sufficiency of an expert's basis generally or always go to weight and not admissibility. Rather it means that once the court has found the admissibility requirement to be met by a preponderance of the evidence, any attack by the opponent will go only to the weight of the evidence.

It will often occur that experts come to different conclusion based on contested sets of facts. Where that is so, the preponderance of the evidence standard does not necessarily require exclusion of either side's experts. Rather, by deciding the disputed facts, the jury can decide which side's experts to credit.

[Rule 702 requires that the expert's knowledge must "help" the trier of fact to understand the evidence or to determine a fact in issue. Unfortunately, some courts have required the expert's testimony to "appreciably help" the trier of fact. Applying a higher standard than helpfulness to otherwise reliable expert testimony is unnecessarily strict.]

Rule 702(d) has also been amended to provide that a trial judge should exercise gatekeeping authority with respect to the opinion ultimately expressed by a testifying expert. A testifying expert's opinion should stay within the bounds of what can be concluded by a reliable application of the expert's basis and methodology.

[Option 1: For example, a forensics expert may not be permitted to testify to a "zero rate of error" if the methodology is subjective and thus necessarily is subject to error.]

[Option 2: For example, a forensics expert who states or implies that a method or conclusion is "infallible," "certain," or "error-free" will by definition be stating an opinion that cannot reasonably be drawn, because such statements cannot be empirically supported. Also, many forensic processes do not comport with the scientific method, so testimony that such a process is "scientific" is not supported --- and is prohibited under this amendment.]

Testimony that mischaracterizes the conclusion that an expert's basis and methods can reliably support undermines the purposes of the Rule and requires intervention by the judge. Just as jurors are unable to evaluate meaningfully the reliability of scientific and other methods underlying expert opinion, jurors lack a basis for assessing critically the conclusions of an expert that go beyond what the expert's basis and methodology may reliably support.

Nothing in the amendment requires the court to nitpick an expert's opinion in order to reach a perfect expression of what the basis and methodology can support. The Rule 104(a) standard does not require perfection. On the other hand, it does not permit the expert to make extravagant claims that are unsupported by the expert's basis and methodology.

2. Draft Two – Adding Rule 104(a) Language to Rule Text and Adding an Overstatement Limitation

Rule 702. Testimony by Expert Witnesses

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates by a preponderance of the evidence that:

- (a) ~~the expert's~~ witness's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) ~~the expert~~ witness has reliably applied the principles and methods to the facts of the case; and
- (e) the witness does not overstate the conclusions that may be drawn from a reliable application of the principles and methods

Draft Committee Note

Rule 702 has been amended in two respects. First, the Rule has been amended to clarify and emphasize that the admissibility requirements set forth in the Rule must be established by to the court a preponderance of the evidence. *See* Rule 104(a). Of course the Rule 104(a) standard applies to most of the admissibility requirements set forth in the Evidence Rules. *See Bourjaily v. United States*, 483 U.S. 171 (1987). But unfortunately many courts have held that the critical questions of the sufficiency of an expert's basis, and the application of the expert's methodology, are generally questions of weight and not admissibility. These rulings are an incorrect application of Rules 702 and 104(a), and are rejected by this amendment.

There is no intent to raise any negative inference regarding the applicability of the Rule 104(a) standard of proof for other rules. The Committee concluded that emphasizing the preponderance standard in Rule 702 specifically was made necessary by the courts that have ignored it when applying the reliability requirements of that Rule.

The amendment clarifies that the preponderance standard applies to the three reliability-based requirements added in 2000. But of course other admissibility requirements in the rule --- such as that the expert must be qualified --- are governed by the Rule 104(a) standard as well. The

amendment focuses on subdivisions (b)-(d) because those are the requirements that many courts have incorrectly determined to be governed by the more permissive Rule 104(b) standard.

Of course some challenges to expert testimony will raise matters of weight rather than admissibility even under the Rule 104(a) standard. For example, if the court finds by a preponderance of the evidence that an expert has relied on sufficient studies to support an opinion, the fact that the expert has not read every single study that exists will raise a question of weight and not admissibility. But this does not mean, as certain courts have held, that arguments about the sufficiency of an expert's basis always or generally go to weight and not admissibility. Rather it means that once the court has found the admissibility requirement to be met by a preponderance of the evidence, any attack by the opponent will go only to the weight of the evidence.

It will often occur that experts come to different conclusion based on contested sets of facts. Where that is so, the preponderance of the evidence standard does not necessarily require exclusion of either side's experts. Rather, by deciding the disputed facts, the jury can decide which side's experts to credit.

[Rule 702 requires that the expert's knowledge must "help" the trier of fact to understand the evidence or to determine a fact in issue. Unfortunately, some courts have required the expert's testimony to "appreciably help" the trier of fact. Applying a higher standard than helpfulness to otherwise reliable expert testimony is unnecessarily strict.]

Rule 702 has also been amended to provide that an expert may "not overstate" the conclusions that can be drawn from a reliable application of the expert's principles and methods, and emphasizes that the court must regulate conclusions of experts even if they are employing a reliable method. Testimony that inaccurately states the conclusion that an expert's methods can reliably support undermines the purposes of the Rule and requires intervention by the judge as gatekeeper. Just as jurors are unable to evaluate meaningfully the reliability of scientific and other methods underlying expert opinion, jurors lack a basis for assessing critically the conclusions that an expert's methodology may reliably support.

The amendment is especially pertinent to testimony of forensic experts. Forensic experts often (explicitly or implicitly) express opinions about probabilities – for example, when comparing features to assess the possible origin of an evidence sample. It is important that the expert accurately inform the factfinder of the meaning of the results that are reached. A forensic expert who states or implies that a method or conclusion is "infallible," "certain," or "error-free" will by definition be stating an opinion that cannot reasonably be drawn, because such statements cannot be empirically supported. Also, many forensic processes do not comport with the scientific method, so testimony that such a process is "scientific" is not supported --- and is prohibited under this amendment.

Under the amendment the expert must accurately state the meaning of the results found by the expert. Accurate testimony will ordinarily include a fair assessment of the rate of error of the methodology employed, based where appropriate on empirical studies of how often the method

produces correct results, as well as other relevant limitations inherent in the methodology. Claims of a match, or of probabilities based only on the expert's experience, without empirically valid support, would not be admissible because they are not reasonably drawn from the method used.

Claims that a forensic expert expresses an opinion to a "reasonable degree of [scientific/forensic] certainty" should be strictly scrutinized under the amendment. That phrase has no scientific meaning; it was developed by lawyers, not scientists. See National Commission on Forensic Science, *Testimony Using the Term "Reasonable Scientific Certainty"*, <https://www.justice.gov/ncfs/file/795146/download> ("Rather than use 'reasonable...certainty' terminology, experts should make a statement about the examination itself, including an expression of the uncertainty in the measurement or in the data. The expert should state the bases for that opinion (e.g., the underlying information, studies, observations) and the limitations relating to the results of the examination."). Examples of properly verified conclusions, when supported by the data and methodology, include statements such as "cannot be ruled out" or "more likely than not." Of course this amendment does not bar testimony that satisfies a state law standard of proof in cases where state law provides the rule of decision.

Nothing in the amendment requires the court to nitpick an expert's opinion in order to reach a perfect expression of what the basis and methodology can support. The Rule 104(a) standard does not require perfection. On the other hand, it does not permit the expert to make extravagant claims that are clearly unsupported by the expert's basis and methodology.

Reporter's Note: If a subdivision (e) is added to regulate overstatement, then the amendment to (d)--- requiring a greater focus on the expert's opinion --- should not be included. The proposed change to (d) while relatively minor, is likely to create confusion when considered with the overstatement provision. There would obviously be some overlap in the two provisions. As the amendment to (d) was offered as a compromise on the overstatement question, it would make no sense to enact both the compromise and the explicit rule against overstatement.